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338

DATE MAILED:

05/29/90

☒ This application has been examined ☒ Responsive to communication filed on 3-19-90 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                  |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-91 are pending in the application.  
Of the above, claims 1-6, 9, 12-15, and 17-51 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☒ Claims 85-89 are allowed.
4. ☒ Claims 7, 8, 10, 11, 16, 52-84, 90, and 91 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit 338

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

Claims 52, 70, 73 and 76 are rejected under 35 U.S.C. 102(a) as being anticipated by Moise. Moise shows blood containing housing means 16, 12, a rotary power device 14, bearing means 40, an exposed junction 36 which is neither hemolytic nor thrombogenic (column 1, lines 65-66), and impeller 18. See column 1, lines 35-44 and lines 61-66.

In regard to claim 70, mechanical thrust bearing is provided by the housing 12. In regard to claim 76, although bearing fluid rather than blood is intended to occupy the gap between the shaft 20 and the sleeve, the structure of the bearing means as claimed is clearly anticipated by Moise.

Claims 55-57, 64 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On line 4 of claim 64 and 67, "said annular blood channel" lacks antecedent basis. In claims 55-57, the term "such as" is considered to be indefinite as to the scope of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and

process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure. There is only brief mention on the idea of using control means to vary the cardiac output but no description of any of the elements involved and no discussion as to how the "physiological needs" are measured or determined on a continual basis.

Claims 11, 58-60, 90 and 91 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

Claims 54, 66, 69, 72, 75 and 84 are rejected under 35 U.S.C. 102(a) as being anticipated by Olsen et al. The bearing means includes the array of permanent magnets and electromagnets 11, 13, 36, 38, 39 (figure 2). Regarding hemolysis and thromogenesis, note the general discussion in column 4, lines 30-62, and particularly the fact that no mechanical bearings are used and that wear and friction is substantially eliminated. Olsen et al. disclose means for reducing cavitation, stagnation, and the like, as shown, for example, by septum 224 in figure 9.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

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A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 7, 8, 10, 16 and 61 are rejected under 35 U.S.C. 103 as being unpatentable over Moise. Moise does not specifically point out preferred dimensions for the anti-thrombogenic blood pump. However, in view of the fact that the pump is to be implantable and on the order of magnitude of the blood stream, a compact size and configuration for residing within the natural heart ~~natural heart~~ would have been within the realm of obvious variants of the embodiments discussed by Moise. In regard to claim 10, an outer layer for facilitating tissue ingrowth is well known in the art of biomedical implants and would thus have been an obvious provision for stability and permanence.

Claims 52-54 and 58-84 are rejected under 35 U.S.C. 103 as being unpatentable over Wampler '712 in view of Olsen et al. Wampler shows all the elements of independent claims 52-54 except for the rotor means 44 being magnetically actuated. One of ordinary skill in the art would have been motivated to consider the

structural scheme of Wampler for use as a self-contained pump (such as that of Moise) because of its effectiveness in preventing thrombosis via purge fluid 50 (Figure 2 of Wampler). It would thus have been obvious to add permanent magnets and electromagnets, as taught by Olsen et al., for example, at appropriate locations on the movable and fixed portions of Wampler because of their well known usage in blood pumps.

In regard to claims 79-81, Wampler shows a small gap near elements 52 and 56 at which the purge fluid enters the bloodstream; stagnation and hence thrombus accumulation is thus prevented at this location.

Claims 55-57 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112 and to include all of the limitations of the base claim and any intervening claims.

Claims 85-89 are allowable over the prior art of record.

Applicant's arguments with respect to the Dorman invention are deemed to be moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, THIS ACTION IS MADE FINAL. See MPEP 706.07(a). Applicant is reminded of the extension of time policy set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE (3) MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO (2) MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE (3) MONTH SHORTENED STATUTORY

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PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX (6) MONTHS FROM THE DATE OF THIS FINAL ACTION.

The Information Disclosure Statement received on March 19, 1990, has not been considered because the particular relevancy of each reference to the instant invention has not been given. Most of the references listed are deemed by Applicant not to be of particular relevance, in fact.


Any inquiry concerning this communication should be directed to Mr David Willse at telephone number 703-557-3125.



D. Willse:wl

5/21/90

5/24/90

  
RANDALL L. GREEN  
SPE  
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